

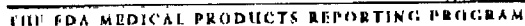
Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

12851



0 - FRONT



Page 1 of 2

FDA Use Only

See QMB statement on reverse

Triage Unit

80867

12851

1. Patient Identifier [REDACTED] In confidence	2. Age at time of event: 22 or _____ Date of birth: [REDACTED]	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or 89.1 ____ kgs
--	--	---	---

1 ☒ Adverse event and/or ☐ Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

☐ death (mo/day/yr)

☒ life-threatening

☒ hospitalization initial or prolonged

☐ disability

☐ congenital anomaly

☐ required intervention to prevent permanent impairment/damage

☐ other:

3. Date of event 3-31-98	4. Date of this report 4-8-98
-----------------------------	----------------------------------

5	Describe event or problem
---	---------------------------

Patient collapsed at health club while lifting weights. Ventricular fibrillation/ cardiac arrest and seizure. Patient currently unresponsive with hypoxic encephalopathy.

"Ripped Force" was consumed the day the patient collapsed, according to friends.

This "supplement" contains:

ephedrine	340 mg
caffeine	1000 mg
potassium	90 mg

6 Relevant tests/laboratory data, including dates

3-31-98 Theophylline = 11.0

Drug screen positive for opiates

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

Hx: Asthma
Meningitis

1. Name (give labeled strength & mfr/labeler, if known) Products
#1 Ripped Force 532 ml American Body Builder
Walterboro, SC 29488

2 Dose, frequency & route used #1 532 ml #2	3 Therapy dates (if unknown, give duration) Imm/In (or best estimate) #1 3-31-98 #2
--	---

4. Diagnosis for use (indication) #1 <u>none - supplement</u> #2	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input checked="" type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
---	---

6. Lot # (if known)	7. Exp. date (if known)	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> 8006 apply
#1	#1	8. Event reappeared after reintroduction
#2	#2	

#2	#2	11	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input checked="" type="checkbox"/> doesn't apply
9. NDC # (for product problems only)		#2	<input type="checkbox"/> yes	<input type="checkbox"/> no	<input type="checkbox"/> doesn't apply

10. Concomitant medical products and therapy dates (exclude treatment of event)

* American Body Building Products
Walterboro, SC USA 29488 1-800-627-0627
Home Rx:
Patient on theophylline (ventolin) - dose
unknown

D. Suspect medical device

1. Brand name

2. Type of device

3. Manufacturer name & address
ALDWORTH

APR 09 1998

4. Operator of device

☐ health professional

☐ lay user/patient

☐ other:

RECEIVED	5 Expiration date (month/year)
----------	-----------------------------------

model #

7. If implanted, give date (month/year)

RECEIVED

8. If explained, give date (m/d/yyyy)

APR 22 1979

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☒ no ☐ returned to manufacturer on (month/year)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1	Name, address & phone #
	[REDACTED]

2. Health professional? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO	3. Occupation Pharmacist	4. Also reported to <input type="checkbox"/> manufacturer
--	-----------------------------	--

5 If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒ ☐ user facility
☐ distributor



Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

or FAX to:
1-800-FDA-0178

000001

Manufactured & Distributed by:
American Body Building Products
Walterboro, SC USA 29488
1-800-627-0627
www.getbig.com

2012

80867

Directions: Begin drinking Ripped Force 20min B4 workout + cont
to sup during workout. Finish 15min B4 training complete

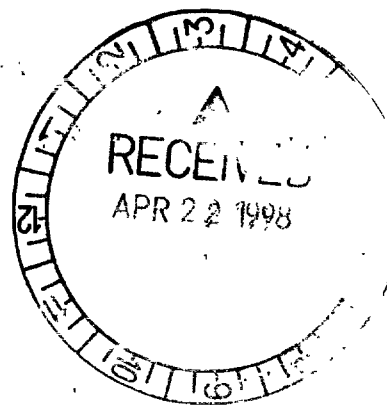
Ing: H₂O, maltodextrin, Hi Fructose Corn Syrup,
Crystalline Fructose, Natural + Artificial Flavors
(Flavors, modified food starch, glycerol esters of wood rosin,
Brominated vegetable oil), guarana, citric acid, ma Huang, → Huang
L-Carnitine, phosphoric acid, K⁺ sorbate (antimicrobial agent)
K⁺ benzoate (preservative) Aspartame, Vit C, K⁺ Gluconate,
Niacin, Inositol, Choline Cl., Chromium picolinate.

K = 90mg

Ma Huang, 6% Ephedrine (Ephedra sinica) (leaf) 340mg

Guarana, 10% Caffeine (Paullinia Cupana) (fruit) 1000mg

Above drink used day pt collapsed.



000002

1. COMPLAINT NUMBER	KAN-6540 12851
2. DATE OF COMPLAINT (Month/Day/Year)	4-23-98

3.	FORM OF COMPLAINT (1) <input checked="" type="checkbox"/> TELEPHONE (2) <input type="checkbox"/> LETTER (3) <input type="checkbox"/> VISIT	4. SOURCE OF COMPLAINT (1) <input type="checkbox"/> CONSUMER (2) <input type="checkbox"/> GOVERNMENT <input type="checkbox"/> L <input type="checkbox"/> S <input type="checkbox"/> F	(3) <input type="checkbox"/> TRADE SOURCE (4) <input checked="" type="checkbox"/> OTHER (Indicate in Remarks)
5.	a. NAME AND ADDRESS (Include Zip Code) <div style="background-color: black; height: 40px; width: 100%;"></div>		b. AREA CODE AND TELEPHONE NUMBER HOME () WORK ()
6.	a. DESCRIPTION OF COMPLAINT/INJURY A 22 yr old male suffered a coma and remained in a coma since 3-31-98 after consuming a body-building supplement.		
7.	a. EIB (HFC-161) NOTIFIED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES DATE 4-23-98	b. TYPE SYMPTOMS ONSET (HR.) 1. <input type="checkbox"/> VOMITING _____ 2. <input type="checkbox"/> NAUSEA _____ 3. <input type="checkbox"/> DIARRHEA _____ 4. <input type="checkbox"/> FEVER _____ 5. <input type="checkbox"/> SKIN/EYE IRR. _____ 6. <input type="checkbox"/> HEADACHE _____ 7. <input checked="" type="checkbox"/> OTHER <u>coma</u> <u>unknown</u>	c. ATTENDING HEALTH PROFESSIONAL (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, and phone number) <div style="background-color: black; height: 40px; width: 100%;"></div>
		d. HOSPITALIZATION REQUIRED (1) <input type="checkbox"/> NO (2) <input checked="" type="checkbox"/> YES (If "yes" give name, address, phone number and dates) hospitalized until present time	
8.	a. BRAND NAME <u>Ripped Force</u> c. SIZE AND PACKAGE TYPE <u>1/18 fl. oz. bottle</u> e. PACKAGE CODE/SERIAL NUMBER/ETC. <u>unknown</u> EXPIRE BY DATE:	b. PRODUCT NAME <u>Body Building Food Supplement</u> d. NAME AND LOCATION OF STORE WHERE PURCHASED <u>Unknown</u> f. DATE PURCHASED <u>unknown</u> g. PRODUCT USED (if "yes" enter date) (1) <input type="checkbox"/> NO (2) <input type="checkbox"/> YES h. AMT REMAINING	
9.	a. HOME DISTRICT <u>ATL-DO</u> b. C.F. NO. <u>1061110</u>	c. NAME AND LOCATION OF FIRM (Include Zip Code) <u>American Body Building Products</u> <u>Walterboro, SC 29488</u> d. IMPORT PRODUCT (1) <input checked="" type="checkbox"/> NO (2) <input type="checkbox"/> YES	
10.	a. PROBLEM KEYWORD (1) CODE (2) DESCRIPTION <u>RX</u> <u>Coma</u> b. EVALUATION (1) <input type="checkbox"/> NOT AN FDA OBLIGATION (2) <input type="checkbox"/> OBLIGATION, NO VIOLATION (3) <input checked="" type="checkbox"/> FDA ACTION INDICATED (4) <input type="checkbox"/> INSUFFICIENT INFORMATION UNABLE TO EVALUATE	c. DISPOSITION (1) <input checked="" type="checkbox"/> IMMEDIATE FOLLOW-UP (2) <input type="checkbox"/> F/U NEXT EI (3) <input type="checkbox"/> CLOSED WITHOUT FURTHER INVESTIGATION (4) <input type="checkbox"/> REFERRED TO OTHER FEDERAL AGENCY (Closes File) (5) <input type="checkbox"/> REFERRED TO STATE/LOCAL AGENCY (Closes file) (6) <input type="checkbox"/> REFERRED TO OTHER FDA _____ DISTRICT	11. PRODUCT CODE 12. INFORMATION COPIES TO; <div style="display: flex; justify-content: space-between;"> <div> <input type="checkbox"/> HFB-100 <input type="checkbox"/> HFD-730 <input type="checkbox"/> HFV-236 </div> <div> <input type="checkbox"/> HFZ-343 <input type="checkbox"/> HFC-161 <input checked="" type="checkbox"/> HFS-635 </div> </div>
REMARKS <div style="text-align: right; font-style: italic; font-size: 1.2em;"> See Routing on memo of F/U - PMW 4/2/98 </div>			
NAME AND TITLE <div style="text-align: center; font-family: cursive; font-size: 1.5em;">Margaret A Smith</div>		DATE <div style="text-align: center; font-size: 1.5em;">000003</div>	

COMPLAINT JURY FOLLOW-UP

1. COMPLAINT NUMBER

KAN-6540

2. ACTION REQUESTED

- (1) ☒ INVESTIGATION
(2) ☐ COLLECT SAMPLE
(3) ☐ INSPECTION
(4) ☐ OTHER

(a). REMARKS (Additional details)

(b) REQUESTING OFFICIAL'S NAME AND TITLE

Margaret A. Smithers, CSO

(c) DATE REQUESTED

ASAP

(d) PRODUCT NAME

Ripped Force

3. ASSIGNED TO:

Margaret A. Smithers

(a) DUE BY

4. ACTION TAKEN

- (1) ☒ INVESTIGATION
(2) ☐ SAMPLE COLLECTED
(3) ☐ INSPECTION
(4) ☐ NONE

(a) SAMPLE NUMBER(s)

None

(b) DESCRIPTION OF ACTION TAKEN

See attached Memo

98 JUN -8 P2:27

RECEIVED
CLINICAL RES. AND
& REVIEW/OSN HFS-452

(c) ACTION OFFICIAL'S NAME AND TITLE

Margaret A. Smithers, CSO

(d) ACTION DISTRICT

KAN-6540

(e) DATE COMPLETED

6-1-98

5. MANUFACTURER/DISTRIBUTOR/DEALER RESPONSIBLE

(a) HOME DIST.

ATL-DO

(c) NAME AND ADDRESS

American Body Building Products
Walterboro, SC 29488

6. PROGRAM DATA

(a) OPERATION

13

(b) PAC

21R301

(c) PRODUCT CODE

54FCT09

(b). CF NO.

1061110

(d) EMP. HOME DIST.

KAN

(e) EMP. NO.

264

(f) POS CL.

2

(g) HOURS

79%

7. EVALUATION

- (0) ☐ PENDING
(1) ☐ NO ACTION INDICATED (NAI)
(2) ☐ VOLUNTARY ACTION INDICATED (VAI)
(3) ☐ OFFICIAL ACTION INDICATED (OAI)
(4) ☐ NOT AN FDA OBLIGATION
(5) ☒ REFERRED TO HOME DISTRICT
(6) ☐ INSUFFICIENT INFO. UNABLE TO EVAL.

8. FINAL DISPOSITION

- (1) ☐ FOLLOW-UP NEXT EI (5) ☐ INJUNCTION/PROSECUTION
(2) ☐ WARNING LETTER (6) ☐ REFERRED TO OTHER AGENCY
(3) ☐ CITATION (7) ☐ RECALL
(4) ☐ SEIZURE (8) ☐ NO ACTION

9. INFO. COPIES TO

- ☐ HFB-100
☐ HFD-730
☐ HFV-236
☐ HFZ-343
☐ HFC-161
☒ HFS-235

REMARKS

ATL-DO: FYI.
KRM/SC80

NAME AND TITLE OF DISPOSITION OFFICIAL

DISPOSITION

DISPOSITION DATE

Adverse Event Questionnaire

Complaint Number: KAN-6540Investigator: Margaret A. Smither

Consumer Information		
Date of Report: <u>4-23-98</u> MM/DD/YY	Initial Report Source: <input type="checkbox"/> ORA Consumer Injury <input type="checkbox"/> Telephone <input type="checkbox"/> Correspondence <input type="checkbox"/> MedWatch <input type="checkbox"/> USP <input type="checkbox"/> PQRS <input type="checkbox"/> Poison Control <input type="checkbox"/> CDC	
Name: <u>[REDACTED]</u>	Gender: <input type="checkbox"/> F <input checked="" type="checkbox"/> M	Age: <u>22</u>
Race: <input checked="" type="checkbox"/> 1-White <input type="checkbox"/> 2-Black <input type="checkbox"/> 3-Asian/Pacific Islander <input type="checkbox"/> 4-Native American <input type="checkbox"/> 5-Hispanic <input type="checkbox"/> 8-Other <input type="checkbox"/> 9-Unknown		
Information on Adverse Event		
Date of Adverse Event: <u>3-31-98</u> Previous Adverse Effects to Product Type: <input type="checkbox"/> Yes <input type="checkbox"/> No <u>Unknown, in come</u>	Give the site of consumption/ingestion (e.g. home, restaurant, office): <u>[REDACTED]</u>	
<p>The following information relates to the consumers' use of the product.</p> <p>Describe the adverse event (including symptoms and the time lapse from using product to onset of symptoms): Consumer collapsed during workout after using Ripped Force Drink.</p> <p>How long did the symptoms last? <u>Continues to remain in vegetative coma.</u> Give the circumstances of exposure (i.e. how much was taken, how was the product taken, how often was it taken, etc.). <u>Ripped force was consumed at rate of 1 to 3 bottles three times a week.</u></p> <p>List all Medication(s), Dietary Supplement(s), Food(s), and other product(s) used at the time of the event: <u>Theo-Dur, Ventolin, Tylenol</u></p> <p>Did event abate after use of suspected product stopped or dose reduced: <input type="checkbox"/>Yes <input type="checkbox"/>No <input checked="" type="checkbox"/>Unknown Did symptoms reoccur after reintroduction of suspected product: <input type="checkbox"/>Yes <input type="checkbox"/>No <input checked="" type="checkbox"/>Unknown <input type="checkbox"/>Not Applicable Did symptoms reoccur after using other products with the same ingredients: <input type="checkbox"/>Yes <input type="checkbox"/>No <input checked="" type="checkbox"/>Unknown <input type="checkbox"/>Not Applicable</p>		
Medical Information		
Was a health care provider seen?: <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No Give health care provider's name, address and telephone number: <u>[REDACTED]</u>		
Occupation of Health Care Provider: <input type="checkbox"/> MD <input type="checkbox"/> Osteopath <input type="checkbox"/> Naturopath <input type="checkbox"/> Nurse <input type="checkbox"/> Pharmacist <input checked="" type="checkbox"/> Other (specify) <u>Hospital</u>		
What medical tests were performed and what were the results? <u>X-rays, CT, urinalysis, bloodwork, EKG, EEG</u> What was the medical diagnosis? <u>Cardiac arrest and hypoxic encephalopathy</u> What treatment(s) was given (e.g., drugs, other)? <u>CPR, Shocked 5 times, intubated, stomach tube, Morphine, Epinephrine, Lidocaine, atropine</u>		
Were there any preexisting condition(s)/treatment(s)? (If YES, list them including allergies, and chronic diseases): <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <u>Asthma</u>		

JUN -8 2:27

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSM HFS-452

390

000005

Product Category

1. Adverse event attributed to:

☐ Medical Food (under medical supervision) ☐ Infant Formula☒ Dietary Supplement (a vitamin; an essential mineral; a protein; a herb or similar nutritional substances including botanicals such as ginseng and yohimbe; amino acids; extracts from animal glands, garlic extract; fish oils; oil of evening primrose; fibers such as psyllium and guar gum; compounds not generally recognized as food or nutrients, such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid, and rutin; and mixtures of these ingredients)☐ Other (traditional food) _____Other Product Problems2. ☐ Foreign Object
(specify): _____3. ☐ Other (specify): _____

Information on Suspected/Alleged Product

Give the product name and manufacturer as listed on the label (including the recommended dosage/serving size, recommended duration of use, and indications for use as listed on the label):

Ripped Force manufactured by American Body Building Products,
Walterboro, SC 29488

List product ingredients (if ingredients are suspected to be present, but not verified, list as suspected):

☐ Check here if ingredients are unknown

See Attached

If a particular ingredient is suspected of contributing to the adverse event, please indicate the appropriate category below:

☐ Aspartame☐ Monosodium Glutamate☐ Sulfite☒ Other _____☐ Unknown☐ Color Additive (please specify) _____Is the product label available, if yes submit a quality copy along with this questionnaire: ☒ Yes ☐ No
☐ Unknown Product Sample Available: ☐ Yes ☐ No ☐ Unknown

Outcome Attributed to Adverse Event:

(If yes, include pertinent medical records)

Death: ☐ Yes ☒ NoLife-Threatening: ☒ Yes ☐ NoHospitalization: ☒ Yes ☐ No (if YES, indicate if initial or prolonged) ProlongedRequired intervention to prevent permanent impairment/damage: ☐ Yes ☐ NoDid the adverse event result in a congenital anomaly: ☐ Yes ☒ No
Permanent impairment occurred

000006



DEPARTMENT OF HEALTH & HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE
U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM

DATE : April 23, 1998
To : File - KAN6540

Firm:

CFN:
FROM : Margaret A. Smithers, Investigator
[REDACTED]

SUBJECT : Follow-up Investigation


On 4-23-98, WCH-RP received a telephone call from [REDACTED]

[REDACTED] who reported a 22 year old male who remained in a vegetative coma after a collapse 3-31-98 at [REDACTED]. The patient had collapsed, seized, suffered ventricular fibrillation/cardiac arrest, and remained unresponsive with hypoxic encephalopathy. The patient, according to his friends, had consumed a bottle of Ripped Force, a body-building supplement. The hospital had filed a Medwatch form, copy of which is attached as Exhibit 2. A bottle of Creatine body-building supplements had been found in the patient's gym bag.

DATE: JUNE 2, 1998

TO: HFS-635, -636, -452, HFC-134 & DIB/HFR-SE150

This memo and attachments are the results of KAN-DO F/U to the complaint involving the reaction of an individual to the product "Ripped Force," including affidavits from appropriate and knowledgeable physicians, mother and "friend" attesting to circumstances and medical condition (cause and diagnosis).


Robert R. Wilson/SCSO/HFR-SW350

O: ATL-DO/HFR-SE150: DIB (all) cc: KAN Complt file - KAN6540 (all)
cc: HFC-134/Mark Fow (all) cc: HFS-635/Bridgette Wallace (all)
cc: HFS-636/Brenda Aloï (memo only)
cc: HFS-452/Lori Love (memo only)
cc: W-RP (memo) cc: R/F (memo)

98 JUN -8 P2:27

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-452

000007

April 23, 1998
Subject - KAN6540
Page 2

The Medwatch form states the patient had collapsed while lifting weights. The diagnosis is ventricular fibrillation/cardiac arrest and seizure and unresponsive with hypoxic encephalopathy. The friends of the patient had reported to hospital officials he had consumed Ripped Force the day he collapsed. The ingredients of the supplement were: ephedrine 340 mg, caffeine 1000 mg, and potassium 90 mg. Medications and drugs found in the patient's system were Theophylline and opiates. The medical history of the patient included asthma and meningitis. A bottle of Creatine had been found in the patient's gym bag the day of his collapse.

The Ripped Force labeling provided to the hospital by the patient's friend reads in part "***Manufactured and Distributed by: AMERICAN BODY BUILDING PRODUCTS Walterboro, SC USA 29488 1-800-627-0627 *** Phenylketonurics: Contains phenylalanine***Diabetic/Hypoglycemics: Use only under a physician's supervision***Directions: Begin drinking RIPPED FORCE 20 minutes before your workout and continue to sip during the workout. Finish drinking 15 minutes before training is completed.***Supplement Facts Serving Size 1 Bottle (532 ML/18 FL. OZ) Amount Per Serving Calories 90 Total Fat 0 g Total Carbohydrate 23 g Sugars 12 g Protein 0g Vitamin C (as ascorbic acid) 2 mg Niacin 10 mg Phosphorus (as phosphoric acid from maltodextrin) 60 mcg Chromium (as picolinate) 200 mcg Sodium (from water, maltodextrin and flavor) 65 mg Potassium (as sorbate, benzoate and gluconate, from maltodextrin) 90 mg Ma Huang, 6% Ephedrine (Ephedra sinica) (leaf) 340 mg Guarana, 10% Caffeine (Paullinia Cupana) (fruit) 1,000 mg L-Carnitine 250 mg***INGREDIENTS: WATER, MALTODEXTRIN, HIGH FRUCTOSE CORN SYRUP, CRYSTALLINE FRUCTOSE, NATURAL AND ARTIFICIAL FLAVORS (FLAVORS, MODIFIED FOOD STARCH, GLYCEROL ESTERS OF WOOD ROSIN, BROMINATED VEGETABLE OIL, GUARANA, CITRIC ACID, MA HUANG, L-CARNITINE, PHOSPHORIC ACID, POTASSIUM SORBATE (ANTIMICROBIAL AGENT), POTASSIUM BENZOATE (PRESERVATIVE), ASPARTAME, ASCORBIC ACID, POTASSIUM GLUCONATE, NIACIN, INOSITOL, CHOLINE CHLORIDE, CHROMIUM PICOLINATE.***"Copy of the labeling provided to the hospital is attached as Exhibit 1.

On 4-24-98 I visited [REDACTED] FDA 482, Notice of Inspection, was issued to [REDACTED], Vice-President, Administrations. The following hospital employees were present during the meeting and provided information: [REDACTED] R.N., Care Coordinator; and [REDACTED] Social Worker. On 4-27-98, I completed my investigation at the hospital meeting with [REDACTED] and [REDACTED] Risk Management Coordinator. The patient is [REDACTED] Mr. [REDACTED] resided with his parents, [REDACTED] Attached as

000008

April 23, 1998
Subject - KAN6540
Page 3

Exhibit 3 is a copy of the medical records for [REDACTED] the patient, provided by the hospital.

The paramedic's report included the following:

Patient was working out when he collapsed. A friend reported he had completed three sets of exercise and gone to get a drink of water. The patient had been laughing and had not complained or displayed any signs of respiratory distress. The friend went to get a drink of water. When he returned, he found the patient lying on the floor in a seizure. Two off-duty RN's initiated CPR after assessing the patient was in cardiac arrest. The patient was described as well nourished and muscular, cyanotic with light purple tinge about his clavicles. No trauma was noted. The patient was pulse less and apneic. Pupils were dilated. Vomitus was found in the airway. Patient was shocked 5 times. Drugs administered were Epinephrine, Lidocaine, and Atropine. Patient was intubated and given an IV. The patient was transported to [REDACTED]

The Emergency Room medical records report:

Crackles and wheezing was observed upon admission to the emergency room. Patient was on a ventilator. Patient had suffered cardiac arrest and not responsive.

The patient was admitted to the hospital. Hospital medical records reveal the following:

Patient remained comatose. Stomach tube for feeding was surgically inserted. Occupation therapy was administered. On 4-8-98 the patient opened his eyes but did not follow verbal commands. The patient did not appear to recognize family and friends. Patient was restrained except when family members were in his room due to his involuntary movements.

The echocardiogram report by [REDACTED] M.D. dated 3-31-98 reported "the left atrial dimensions within normal limits with left atria diameter measured at 2.85 c.m. Normal morphology of the mitral valve leaflets were found with no trace mitral insufficiency and no evidence for stenosis. Mild left ventricular dilation with left ventricular end diastolic diameter measured at a5.81 cm. The upper limits of normal being 5.6 cm. Moderate global hypokinesis is present with ejection fractions calculated from 43% to 47% and estimated ejection fraction closer to 35%-40%. No evidence for delayed diastolic relaxation is present. Dense aortic root with

000009

April 23, 1998
Subject - KAN6540
Page 4

normal morphology and function of the aortic valve leaflets. No evidence for intracardiac mass or thrombi. No evidence for pericardial effusion. See Exhibit 3, Page 60.

The operation report of [REDACTED], M.D. for the placement of a Camino subarachnoid screw and ICP monitor reported "****At the time of the admission, the patient was unresponsive, but was opening his eyes, and would track, but would not do anything to commands and moved all four extremities well with good strength, requiring restraint; although initially he was obtunded, he had come to that point. Now however, seven days after the event, the patient was noted to be less responsive, no longer tracks and was noted to have a decerebrate posturing. Because of this and the question of increased ICP, recommended for ICP monitor.***.

The operation report of [REDACTED], M.D., surgeon, with diagnosis of dysphagia secondary to sudden death syndrom and cerebral nervous system injury, addressed placement of esophagogastroduodenoscopy and percutaneous endoscopic placement of gastrostomy tube. See Exhibit 3, Page 69.

Inpatient Summary Report printed 4-8-98 provides analytical records with Urine Drugs of Abuse Screen for Opiates, Positive, >300 ng/mL. The report has a disclaimer, "No Chain of Custody". See Exhibit 3, Page 103.

The Diagnostic Imaging Report dated 3-31-98 found "****CT of the brain without contrast shows some diffuse edema throughout the supratentorial brain. The cisternal spaces appear fairly well maintained. There is decreased density noted in both occipital lobes, the left more so than the right which is consistent with ischemia in these locations. No evidence for hemorrhage, mass, or extra-axial collections is seen. The visualized portions of the paranasal sinuses are clear.***IMPRESSION: 1. There is some diffuse edema throughout the supratentorial brain with the cisternal spaces appearing fairly well maintained. 2. Low density seen in both occipital regions, left greater than the right which is consistent with ischemic events in these locations.***" See Exhibit 3, Page 122.

The Diagnostic Imaging Report for the chest AP/PA only dated 3-31-98 found "****The patient is intubated with the tip of the ET tube 2 cm proximal to the carina. Heart size and pulmonary vascularity are normal. There is some patch density in the right middle lobe consistent with a small area of atelectasis or infiltrate. The lungs are otherwise clear.***IMPRESSION: 1. ET tube tip as above. 2. There is some density in the right middle lobe consistent with a small area of atelectasis and/or infiltrate.***" See Exhibit 3, Page 3.

000010

April 23, 1998
Subject - KAN6540
Page 5

The Neurodiagnostics Report of Electroencephalogram Study dated 4-1-98 found "****EKG monitor showed sinus tachycardia.***IMPRESSION: Abnormal EEG showing significant amount of background suppression. Constant with post arrest encephalopathy. There is no evidence of seizure.****" See Exhibit 3, Page 150.

The remaining portion of the patient's urine sample collected day of collapse for drug screen was shipped to [REDACTED] by hospital personnel per FDA/CFSAN request.

On 4-24-98, I met with Mr. [REDACTED] mother, [REDACTED] during her visit with her son at the hospital. Mrs. [REDACTED] home address is [REDACTED]. She signed the Medical Records Release which is attached as Exhibit 11. Mrs. [REDACTED] reported the following:

Her son worked for [REDACTED], [REDACTED] collapse during his workout at the gym. [REDACTED] treatment for asthma began before he was three years old. [REDACTED] had a respiratory arrest at age 10 and meningitis when he was 6. His asthma treatment included Theo-Dur tablets twice a day and a Ventolin inhaler as needed and before and after exercise. [REDACTED] was supposed to use the inhaler daily, four times a day. [REDACTED] had not been taking any pain medications on a regular basis. He had taken Tylenol a couple of days before his collapse for a headache and had used his inhaler to relieve asthma wheezing. Prescription medication he was using included Theo-Dur 300 mg twice daily, Ventolin (Albuterol U.S.P. manufactured by Glaxo-Wellcome), and Atrohist Plus SR.

[REDACTED] had gotten off work at 4:30 p.m. and gone to the gym to workout. [REDACTED] a friend of [REDACTED] who was working out with him, told me [REDACTED] had been lifting weights and had went down to pick up more weights and someone saw him stumble. Ambulance personnel performed CPR and shocked [REDACTED] with paddles.

[REDACTED] consumed protein milk shakes several times a day at home and took vitamins and mineral supplements.

[REDACTED], M.D., [REDACTED] is [REDACTED] regular physician.

[REDACTED] affidavit is attached as Exhibit 4. Mrs. [REDACTED] provided me the bottle of Creatine product which was found in [REDACTED] gym bag the day of his collapse. On the night of 4-24-98, I visited Mr. [REDACTED] parents and the following vitamins,

000011

April 23, 1998
Subject - KAN6540
Page 6

minerals, and body building supplements were provided to me by his parents:

1. Creatine
2. Cybergenics Quick Trim 1
3. Cybergenics Quick Trip Quick Time 2
4. Cybergenics Quick Trim Complex 3
5. GNC Times Release Mega Man
6. Joe Weider Dynamic Fat Burners
7. Chocolate Whey Isolated Glutamine Peptide Protein

Labeling of these products are as follows:

1. Partial bottle of Prolab Nutrition Chocolate Whey Protein labeling in part "****8026J31 01/00***ADVANCED HYPO-ABSORPTION WHEY PROTEIN PROLAB NUTRITION IMPROVED ENHANCED FORMULA Chocolate Whey IONIZED WHEY, HYDROLYZED WHEY ISOLATE & GLUTAMINE PEPTIDES Protein The Athlete's #1 Choice in Advanced Muscle Building Protein TWO POUNDS***907.2 GRAMS***Nutrition Facts Serving size: 31.5gm (approx. 1 scoop)***Amount per serving Calories 130 Calories from Fat 16***Total Fat 1.5 gm 2% Saturated Fat .75 gm 6% Cholesterol 45 mg 15% Sodium 55 mg 2% Total Carbohydrate 3.5 gm 1% Dietary Fiber 0.5 gm 2% Sugars 1 gm Protein 24 gm Vitamin A <2% Vitamin C <2% Calcium 18% Iron 2%***Based on a 2000 calorie diet.***Ingredients: Pure ion exchanged, micro ultra filtered whey protein concentrate (Beta Lactoglobulin 18,000 MW/49%, Alpha lactoalbumin 14,2000 MW/23%, Glyco Macro Peptides 16,5000 MW/20%, Bovine Serum Albumin 69,000 MW/4%, Protease Peptone <1%, Lactoferrin <1%, Lacto Peroxidase <1%), Partially hydrolyzed whey protein isolate (Beta lactoglobulin 25,000 MW/55%, Alpha lactoalbumin 15,200 MW/27%, Immunoglobulin 16,500 MW/12%, Bovine Serum Albumin 50,000 MW/5%, Protease Peptone <1%, Lactoferrin <1%, Lacto Peroxidase <1%), Glutamine Peptides, Cocoa Powder (Dutch Process), Natural & Artificial flavor, Lecithin, Acesulfame Potassium, Aspartame*PHENYLKETONURICS: contains phenylalanine***Typical Amino Acid Profile per 100 grams of protein L-Alanine 4.8 gm L-Arginine 2.3 gm L-Aspartic Acid 10.2 gm L-Cystine 1.2 gm L-Glutamic Acid 17.2 gm, L-Glycine 2.0 gm, L-Histidine 1.6 gm L-Isoleucine 8.4 gm L-Leucine 10.5 gm L-Lysine 9.1 gm L-Methionine 1.6 gm L-Phenylalanine 3.1 gm L-Proline 6.1 gm L-serine 5.2 gm L-Threonine 6.2 gm L-Tryptophan 2.1 gm L-Tyrosine 2.4 gm L-Valine 6.0 gm***There are many proteins on the market for you to choose from, so why choose Prolab Nutrition's Advanced Why protein? Allow us to tell you why. We have taken our pure ion exchanged whey protein

000012

April 23, 1998
Subject - KAN6540
Page 7

concentrate and used it to build the newest, most perfectly developed protein you will find anywhere. We have enhanced our pure ion exchanged whey with glutamine peptides and hydrolyzed whey isolate (ISO 94) to bring you the most rapidly absorbed protein formula on the market. Glutamine peptides are popular among athletes due to its ability to increase muscle cell volumization and endurance. Increases in muscle size and endurance are often associated with use of glutamine peptides. Hydrolyzed whey isolate is specially filtered whey protein isolate enzyme treated to form high concentrations of whey peptides. Peptides are links of amino acids in the protein that are more rapidly and more easily absorbed. This advanced formula ends up having the highest bioavailability of ANY protein. Our Advanced Whey is manufactured using a concentrated cold spray drying method and a series of filtration steps that includes cross and micro ultra filtering. This protects the protein from damaging heat and also promotes maximum nitrogen retention to create the best environment for muscle anabolism, making this formula ideal for pre-contest as well as off season training. Advanced Whey highlights:***is enhanced with hydrolyzed whey isolate (ISO 94) that contains rapidly absorbed peptides which have been shown to enhance the anabolic environment of muscle tissue***is enhanced with Glutamine Peptides for enhanced muscle cell volume and performance***contains no denatured protein***has a BV rating as high as 159***has a 68% greater nitrogen retention level***is much better absorbed and utilized by the body***contains no purines. Purines are precursors to uric acid and may cause joint soreness***contains high levels of BCAA's which have a muscle sparing effect***is lactose free - will not cause gastric distress***mixes instantly***Suggested Use: Use one or two servings (one or two scoops) per day. Each serving should be mixed with 6 - 8 ounces of your favorite beverage. One serving is recommended after strenuous exercise. This product mixes easy with a spoon, but may also be blended with fruit and ice.***The protein in this bottle is pure protein of only the highest quality. No fillers or sugars are added. Formulated and manufactured for: PROLAB NUTRITION 11 Britton Drive Bloomfield, CT 06002 (860)769-5550***100% NATURAL***

2. Partial bottle of Dynamic Fat Burners Dietary Supplement with labeling in part "***DIETARY SUPPLEMENT Joe Weider DYNAMIC FAT BURNERS 250 CAPLETS With CHROMIUM PICOLINATE and THERMOGENIC HERBS***NUTRITION INFORMATION: Each serving (2 caplets) provide: Chromium (picolinate) 200 mg Choline Bitartrate 400 mg Inositol 200 mg dl-Methionine 75 mg

000013

Psyllium Seed Husks 500 mg Cinnamon Powder 300 mg Mustard Seed Powder 300 mg Uva Ursi Extract 50 mg (min. 20% arbutin) Cayenne 15 mg (oleoresin extract: min. 30,000 SHU) Additional ingredients: Cellulose, Calcium Carbonate, Silica ***Manufactured and distributed by Weider Nutrition Group Salt Lake City, Utah 84104 1-800-I-FLEX-IT***DYNAMIC FAT BURNERS are loaded with Chromium Picolinate (today's hottest diet supplement), Psyllium fiber and the latest thermogenic herbs. Plus lipotropic factors such as choline and inositol to promote the transportation and utilization of fats. SUGGESTED USE Take 1 or 2 caplets with your first meal of the day as a dietary supplement. On workout days, take 1 or 2 tablets 60 minutes prior to workout. NOTE: If you are pregnant, lactating or on prescribed medication, consult your physician before using. KEEP OUT OF THE REACH OF CHILDREN. DIABETICS/HYPOGLYCEMICS: Use only under a physician's supervision.***NL1445A***"

3. Partial bottle of GNC Timed Release Mega Men Multiple Vitamin and Mineral Supplement with labeling in part "****MEN'S****GNC TIMED RELEASE MEGA MEN The Premium Multiple Vitamin and Mineral Supplement Formulated for Men With Nutra Seal Freshness Coating Natural Base High Potency 200 TABLETS***No Sugar No Artificial Colors No Preservatives Sodium Free No Wheat, No Dairy***Distributed by General Nutrition Corporation Pittsburg, PA 15222 USA***DIRECTIONS: As a dietary supplement, take two tablets daily. TWO TABLETS CONTAIN: ANTIOXIDANT SUPPLEMENTS Vitamin A (beta-Carotene 15,000 IU Vitamin A (Acetate) 5,000 IU Vitamin E (d-alpha Tocopheryl Acetate) 100 IU Vitamin C (Ascorbic Acid) 300 mg Selenium (Selenium Yeast) 25 mcg Citrus Bioflavonoids 25 mg Superoxide Dismutase (SOD) 10 mcg Pyconogenol 1 mcg HAIR SUPPLEMENTS Biotin 250 mcg Silica (Silicon Dioxide) 10 mcg Inositol 10 mg L-Cystine 100 mg MALE SUPPLEMENT Zinc (Zinc Oxide) 50 mg Copper (Copper Oxide) 2 mg Oyster Extract 50 mg Prostate Glandular 50 mg Pumpkin Seed 30 mg Damiana Leaves 70 mg Saw Palmetto Berries 50 mg Goldenseal Herb 70 mg Oat Straw 70 mg Nettles Leaves 30 mg Korean Ginseng Root 70 mg B VITAMINS Vitamin B-1 (Thiamine Mononitrate) 30 mg Vitamin B-2 (Riboflavin) 30 mg Vitamin B-3 (Niacin) Vitamin B-6 (Pyridoxine Hydrochloride) 30 mg Vitamin B-12 (Cyanocobalamin) 30 mcg OTHER SUPPLEMENTS Folic Acid 400 mcg Vitamin D (Cholecalciferol) 200 IU Pantothenic Acid (Calcium d-Panthenate) 30 mg Calcium (Dicalcium Phosphate) 275 mg Phosphorus (Dicalcium Phosphate) 210 mg Iodine (Potassium Iodide) 150 mcg Magnesium (Magnesium Oxide) 100 mg, Maganese (Manganese Gluconate) 5 mg Potassium (Potassium Chloride) 30 mg Chromium (Chromium Picolinate) 50 mcg

April 23, 1998
Subject - KAN6540
Page 9

Vitamin K (Phytonadione) 25 mcg Choline (Choline Bitartrate) 10 mg para-Aminobenzoic Acid (PABA) 10 mg In a base of Garlic, Oat Bran, Spirulina, Alfalfa, Parsley, Lecithin, Watercress, Smilax (Sarsaparilla), and Cayenne***Pycogenol is a registered trademark of Horphag Research LTD***MADE WITH THE FOLLOWING: FILLERS: Dicalcium Phosphate BINDERS: Cellulose, Povidone, Gelatin, Mannitol COATING: Food Glaze, Cellulose, Wax, Acetoglycerides, Titanium Dioxide, Corn Starch, Caramel, Vanillin, Xanthan Gum EXCIPIENTS: Stearic Acid, Magnesium Stearate, Silica***55545GX 6 98***"

4. Partial bottle Cybergenics Quick Trim Complex 3 Dietary Supplement with labeling in part "***CYBERGENICS QUICK TRIM COMPLEX 3 Dietary Supplement 36 Caplets Ingredients: Dicalcium Phosphate, Senna Leaves Powder, Licorice, Microcrystalline Cellulose, Bentonite, Fennel, Buckthorn, Cascara Sagrada, Stearic Acid, Croscarmellose Sodium, Pharmaceutical Glaze, Magnesium Stearate, Silica, Citrus Pectin, Psyllium Seed, Apple Pectin, Carrot Powder, Beet Fiber, Red Clover, Echinacea, Prune Powder, Siberian Ginseng, Ginkgo Biloba, Fenugreek, Acidophilus, Aloe Vera, Chlorophyll. Distributed by L & S Research Corporation, Lakewood, NJ 08701 L & S Research Corporation, U.K., London, England QTY 9LG***DIRECTIONS: Take 4 caplets after the mid-day meal beginning on day 6***EXP 11/97 55679***"
5. Partial bottle of Creatine Monohydrate Powder with labeling in part "***100 GM FREE***MAXIMIZE SIZE, STRENGTH & ENDURANCE PROLAB NUTRITION CREATINE MONOHYDRATE Increase Muscle Peak-Torque Production POWDER 100 grams***1/98 EX/00 SK733801 ASSY 99.9% 00043035***PROLAB NUTRITION 11 Britton Drive Bloomfield, CT 06002 (800) PROLAB-1 CREATINE MONOHYDRATE POWDER 100 gm INGREDIENTS: HPLC Pure pharmaceutical grade Creatine Monohydrate. SUGGESTED USE: During the loading phase take one rounded teaspoon (5 grams) 4-5 times per day (20-25 grams total) for 5 days. For maintenance period, take one rounded teaspoon (5 grams) 2-3 times daily. Dissolve in juice or water. Creatine Monohydrate is the most advanced nutritional supplement available for athletes. Research shows an increase in muscle peak torque production (force of contraction), muscle strength and endurance with oral Creatine Monohydrate usage. This may be a result of Creatine Monohydrate's ability to better maintain ATP levels. Creatine users also experienced a decrease in levels of plasma ammonia.***"

000015

April 23, 1998
Subject - KAN6540
Page 10

6. Partial bottle Cybergenics Quick Trim Complex 2 Dietary Supplement with labeling in part "***CYBERGENICS QUICK TRIM COMPLEX 2 Dietary Supplement 56 Caplets***DIRECTIONS: Take 2 caplets prior to the morning meal, and 2 caplets prior to the evening meal.***EXP 11/97-55675***Ingredients: Dicalcium Phosphate, Whey Powder, Microcrystalline Cellulose, Pharmaceutical Glaze, Magnesium Oxide, Choline Bitartrate, Croscarmellose Sodium, Brindall Berry Powder, Stearic Acid, Silica, Magnesium Stearate, Inositol, Oat Fiber, d. l. Alpha Tocopheryl Acetate, Ferrous Fumarate, Kelp, Biotin, Niacinamide, Zinc Oxide, Copper Gluconate, D Calcium Panthothenate, Retinyl Palmitate, Betain HCL, Couchgrass Powder, Corn Silk Powder, Hesperidin Complex, Oxbile Extract, Pancreatin, Papain, Citrus Pectin Cellulose, Wheat Bran, Lecithin Powder, Chromium Dinicotinate Glycinate, d.l. Methionine, Buchu Extract, Carrot Powder, Pyridoxine HCL, Riboflavin, Thiamine HCL, Bromelain, Cyanocobalamin, Cholecalciferol, Folic Acid, Chromium Picolinate % Daily Value per 4 tablets - Vitamin A 50%, Vitamin D 50%, Vitamin B¹ 50%, Vitamin B₂ 50%, Vitamin B₆ 50%, Pantothenic Acid 50%, Vitamin E 50%, Niacin 50%, Folic Acid 50%, Vitamin B₁₂ 50%, Biotin 50%, Vitamine C 50%, Calcium 50, Phosphorus 50%, Iron 50%, Magnesium 50%, Iodine 50%, Copper 50%, Zinc 50%***Distributed by: L&S Research Corporation, Lakewood, NJ 08701***DIABETICS: Use only under a physician's supervision.***"
7. Partial bottle Cybergenics Quick Trim Complex 1 Dietary Supplement with labeling in part "***CYBERGENICS QUICK TRIM COMPLEX 1 Dietary Supplement 12 Caplets***DIRECTIONS: Take one caplet directly after your morning meal and one caplet directly after your evening meal. During days 8 thru 13. EXP 11/97-55674***Ingredients: Dicalcium Phosphate, Couchgrass, Microcyrstalline Cellulose, Pharmaceutical Glaze, Stearic Acid, Croscarmellose, Sodium, Yerba Mate, Silica, Magnesium Stearate, Plaintain Powder, Kola Nut Powder, Touchwood, Cinnamon Powder, Atractylodes, Plaintain Seed, Green Tea, Uva Ursi, Green Papaya, Odorless Garlic Distributed by: L&S Research Corporation, Lakewood, NJ 08701***"

On 4-28-98, I interviewed [REDACTED] friend of [REDACTED] who was with him at the gym the day of his collapse, [REDACTED] reported as follows:

[REDACTED] is his best friend. They did just about everything together. Usually, they were together two to

000016

April 23, 1998
Subject - KAN6540
Page 11

four days a week and on weekends. They worked out six days per week at [REDACTED] rotating their workout:

Monday - Chest and triceps
Tuesday - Back and Biceps
Wednesday - Legs
Thursday - Chest and triceps
Friday - Back and Biceps
Saturday - Legs
Sunday - Free day, no workout

On 3-31-98 [REDACTED] arrived at the gym approximately 15 to 20 minutes before [REDACTED] got to the gym at approximately 4:45 p.m. [REDACTED] was working on his second set of dumbbell exercises. [REDACTED] went to get a drink of water and turned around and looked for [REDACTED]. He saw him on the gym floor. He thought [REDACTED] had tripped and hit his head. He heard him gasp for breath and ran to [REDACTED] truck to get his inhaler. When he got back, people were giving him CPR. [REDACTED] had not complained of feeling crappy, tired, or of an asthma attack. He was laughing and talking before [REDACTED] went for a drink.

The list of supplements found at [REDACTED] home was shown to [REDACTED]. He thought [REDACTED] usage of these were as follows:

1. Creatine - [REDACTED] did use the Creatine, but he was unsure how much.
2. Cyberganics Quick Trim 1 - [REDACTED] purchased the Cyberganics in 1996, but he did not think [REDACTED] had used them recently.
3. Cyberganics Quick Trip Quick Time 2 - [REDACTED] purchased the Cyberganics in 1996, but he did not think [REDACTED] was using this one.
4. Cyberganics Quick Trim Complex 3 - [REDACTED] purchased the Cyberganics in 1996, but he did not think he has used them recently.
5. GNC Times Release Mega Man - [REDACTED] thought this supplement was new. He had not seen [REDACTED] use it.
6. Joe Weider Dynamic Fat Burners - [REDACTED] thought this supplement might be an old product.
7. Chocolate Whey Isolated Glutamine Peptide Protein - [REDACTED] and [REDACTED] used this supplement daily.

000017

April 23, 1998
Subject - KAN6540
Page 12

█████ stated █████ did use the Ripped Force drink, which is sold at █████

█████ affidavit is attached as Exhibit 5.

On 4-30-98 I interviewed █████, Manager, █████ Mr. █████ reported the following:

Mr. █████ was working at the gym on 3-31-98 when █████ collapsed. █████ and █████ have been members of the gym for two years, working out six days a week. Mr. █████ has known █████ since he signed him up as a member, approximately two years. He stated he did not know █████ was an asthmatic until after he became a member but has never seen █████ use an inhaler. He stated █████ looked fair when he came in to work out on 3-31-98. Mr. █████ stated he had seen █████ by the dumb bell rack. He did not see █████ working out. Mr. █████ reported one minute █████ was fine, and the next minute he had collapsed on the floor. Someone came upstairs and said, "█████ passed out. Call 911." He called 911 and ran downstairs to assess the situation. He attempted to check for █████ pulse, could not find a pulse, and was about to start CPR when a nurse came down and told him to get out of the way. The nurse took over and began giving CPR. Another nurse working out at the gym assisted her. Approximately two minutes later, the paramedics arrived. The paramedics bagged █████, shocked him a couple of times, stabilized him, and transported █████ out of the gym.

Mr. █████ stated several food supplements and body building supplements are sold at the gym. No records other than number sold and inventory are maintained. The food supplement and body building supplement shakes are made to order for members by the gym staff. Food supplement drinks such as the Ripped Force drink are offered for sale in the cooler. The member selects the drink and pays the staff member for the drink.

On 4-30-98 I interviewed █████ an employee of █████ Ms. █████ affidavit is attached as Exhibit 6. Ms. █████ reported the following:

Ms. █████ has known █████ for approximately 1 ½ years, both as a member and socially. █████ always drank a Ripped Force prior to a work out. When he finished his workout, he would have a whey protein shake.

000018

April 23, 1998
Subject - KAN6540
Page 13

On 3-31-98, the day of his collapse, [REDACTED] had no complaints, smiled, and did not look tired. She was not aware of any medications he might have been using.

She remembered [REDACTED] running upstairs for [REDACTED] inhaler. While [REDACTED] was down, the people around him were trying to give him his inhaler. He was on his back, gasping for breath. He looked like he was breathing. A dentist, who was a member, was checking for a pulse. She went upstairs to make sure someone had called 911. A nurse had taken over. The paramedics intubated [REDACTED] shocked him, and gave him an IV.

On 5-5-98, I interviewed [REDACTED], M.D., [REDACTED] is his patient. His affidavit is attached as Exhibit 8. Dr. [REDACTED] reported the following:

Dr. [REDACTED] treated Mr. [REDACTED] prior to his collapse on 3-31-98 for a knee sprain in 1996. He provided asthma refill prescriptions and examinations in 1995. In 1994 he saw Mr. [REDACTED] for a foot contusion and a head cold. Medications which have been prescribed include Ultram, Ventolin, Theo-Dur, Ru-Tuss, Intal, Amoxicillin, Predisone, and Asthmacort. He has not prescribed any pain-killer type medication for Mr. [REDACTED]

Mr. [REDACTED] probably coded due to an arrhythmic change. Asthma was not a factor in his collapse. Dr. [REDACTED] agreed with the diagnosis of the cardiologist, [REDACTED] M.D., for Mr. [REDACTED] collapse and cardiac arrest.

On 5-4-98, I interviewed [REDACTED] Owner, [REDACTED] Mr. [REDACTED] reported [REDACTED] did use an asthma inhaler during workouts for asthma. He stated [REDACTED] and [REDACTED] routinely worked out 6 days per week. He could not say whether [REDACTED] consumed the Ripped Force on days they worked out as they did not work out at the [REDACTED] very often. He reported recently the [REDACTED] had received a bad shipment of the Ripped Force. It had a sweet taste like a "Tootsie Pop." When he contacted the manufacturer, he was reportedly told it contained extra Ma Haung and he could sell it anyway. He stated the Ripped Force drink is addictive and people who use it will always use it.

On 5-6-98, I interviewed [REDACTED] M.D., cardiologist [REDACTED] Her affidavit is attached as Exhibit 9. Dr. [REDACTED] reports the following:

000019

April 23, 1998
Subject - KAN6540
Page 14

Dr. [REDACTED] treated [REDACTED] at [REDACTED] [REDACTED] suffered a cardiac arrest during a work out at a gym. The cardiac arrest was most likely a result of the Ephedrine and Caffeine ingredients of the Ripped Force drink combination with the Theo-Dur and Ventolin medications which caused premature ventricular contractions and ventricular tachycardia, and ventricular fibrillation as a side effect resulting in the cardiac arrest of [REDACTED]. The friend who was with Mr. [REDACTED] when he collapsed stated to her [REDACTED] was drinking three of the Ripped Force drinks per day. Mr. [REDACTED] lab tests were void for drugs, no steroids were found, and no toxicity was found. The opiates which were found in the urine test were a result of morphine sulfate administered by the pulmonologist to Mr. [REDACTED] during treatment the day of his collapse.

On 5-8-98, I interviewed [REDACTED] [REDACTED] reported the following:

Dr. [REDACTED] treated [REDACTED] at [REDACTED] as part of his medical care after his collapse during a workout at a gym. Mr. [REDACTED] had suffered a permanent neurological injury during cardiac arrest due to the usage of therapeutic medication with the Ripped Force drink with ephedrine and caffeine. Mr. [REDACTED] suffered sudden death and cardiac arrest. Dr. [REDACTED] stated sudden death from cardiac arrest is not expected with asthma attacks. There were no toxins or street drugs found in Mr. [REDACTED] lab analysis. The opiates found were morphine given the day of Mr. [REDACTED] cardiac arrest. Mr. [REDACTED] did not collapse from asthma. There were no indications of asthmatic distress from Mr. [REDACTED]. His theophylline blood level was at the therapeutic range.

Mr. [REDACTED] has been transferred to the [REDACTED] [REDACTED]. I visited [REDACTED] and his parents on 5-26-98 to obtain [REDACTED] signature on her affidavit. Mr. [REDACTED] is now ambulatory and can feed himself. He does not remember his friends and has to be reminded who they are when his friends visit. He is now able to swallow and can feed himself. He recognizes his parents but his not able to pick them out of photographs. Doctors and family report Mr. [REDACTED] will have long term rehabilitation therapy.

000020

April 23, 1998
Subject - KAN6540
Page 15

EXHIBITS

- 1 - Copy of Ripped Force label provided to the hospital by friends of the patient
- 2 - Copy of MEDWATCH completed by [REDACTED]
- 3 - [REDACTED] Copy of the medical records for [REDACTED] the patient
- 4 - [REDACTED] affidavit
- 5 - Copy of medical records for [REDACTED] from [REDACTED] M.D.
- 6 - [REDACTED] affidavit dated
- 7 - [REDACTED] affidavit dated 5-10-98
- 8 - [REDACTED], M.D., affidavit dated 5-19-98
- 9 - [REDACTED], M.D., affidavit dated 5-20-98
- 10 - [REDACTED] M.D., affidavit
- 11 - Medical Authorization Released signed by [REDACTED] mother of patient

Margaret A. Smithers
Margaret A. Smithers, 264
Investigator, [REDACTED]

000021



DEPARTMENT OF HEALTH & HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE
U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM

DATE : July 23, 1998
To : Brenda Aloï, HFS-636
CFSAN
Thru : Robert R. Wilson, Supervisory Investigator
KAN-DO

Firm:

CFN:
FROM : Margaret A. Smithers, Investigator
[REDACTED]

SUBJECT : KAN-6540 Additional Medical Reports Requested

Attached are the physician's official transfer note/discharge summary from [REDACTED] and a copy of the in-take history and physical records and dismissal summary from [REDACTED] for the complainant, [REDACTED] Mr. [REDACTED] is presently an out-patient at [REDACTED]

EXHIBITS

- 1 - Copy of transfer note/discharge summary from [REDACTED]
- 2 - Copy of in-take history and physical records, [REDACTED]
- 3 - Copy of dismissal summary, [REDACTED]

Margaret A. Smithers
Margaret A. Smithers, 264
Investigator, [REDACTED]

DATE: 7/24/98
To: Brenda Aloï, HFS-636
CFSAN

RECEIVED
8/17/98
HFS-636

Per your request the records are attached.

O: addressee - Aloï/HFS-636(all)
cc: KAN-6540 File (all)
cc: R/F (all)
cc: [REDACTED]

Robert R. Wilson
HFS-636

7/30 000022



DEPARTMENT OF HEALTH & HUMAN SERVICES
U.S. PUBLIC HEALTH SERVICE
U.S. FOOD & DRUG ADMINISTRATION

MEMORANDUM

DATE : July 24, 1998
To : Rich Pendleton, Compliance Officer
Kansas District Office
Thru : Bob Wilson, Supervisory Investigator
Kansas District Office

Firm:

CFN:

FROM : Margaret A. Smithers, Investigator
[REDACTED]

SUBJECT : Amendment Memo 98-688-719, Ripped Force

The following is the labeling for Sub 8, Ripped Force:

Sub 8. The Ripped Force labels in part "****Manufactured and Distributed by: AMERICAN BODY BUILDING PRODUCTS Walterboro, SC USA 29488 1-800-627-0627****Phenylketonurics: Contains phenylalanine***Diabetic/Hypoglycemics: Use only under a

DATE: Aug 12, 1998

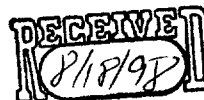
TO: Brenda AL01/CFSAN/HFS-636

Please ATTACH as a continuation to C/R
98-688-719.

R. Wilson
SC80/HFR-SW350

O: Addressee

80: 6V 81 9VA 86.



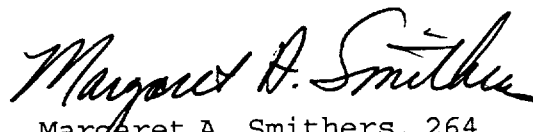

HFS-636

RECEIVED
CLINICAL RESEARCH
& REVIEW/OSN HFS-250

000023


Memo - Amendment to CR 98-688-719, Ripped Force
Date - 7-24-98
Page 2

physician's supervision***Directions: Begin drinking RIPPED FORCE 20 minutes before your workout and continue to sip during the workout. Finish drinking 15 minutes before training is completed.***Supplement Facts Serving Size 1 Bottle (532 ML/18 FL. OZ) Amount Per Serving Calories 90 Total Fat 0 g Total Carbohydrate 23 g Sugars 12 g Protein 0g Vitamin C (as ascorbic acid) 2 mg Niacin 10 mg Phosphorus (as phosphoric acid from maltodextrin) 60 mcg Chromium (as picolinate) 200 mcg Sodium (from water, maltodextrin and flavor) 65 mg Potassium (assorbate, benzoate and gluconate, from maltodextrin) 90 mg Ma Haung, 6% Ephedrine (Ephedra sinica) (leaf) 340 mg Guarana, 10% Caffeine (Paullinia Cupana) (fruit) 1,000 mg L-Carnitine 250 mg***INGREDIENTS: WATER, MALTODEXTRIN, HIGH FRUCTOSE CORN SYRUP, CRYSTALLINE FRUCTOSE, NATURAL AND ARTIFICIAL FLAVORS (FLAVORS, MODIFIED FOOD STARCH, GLYCEROL ESTERS OF WOOD ROSIN, BROMINATED VEGETABLE OIL, GUARANA, CITRIC ACID, MA HUANG, L-CARNITINE, PHOSPHORIC ACID, POTASSIUM SORBATE (ANTIMICROBIAL AGENT), POTASSIUM BENZOATE (PRESERVATIVE), ASPARTAME, ASCORBIC ACID, POTASSIUM GLUCONATE, NIACIN, INOSITOL, CHOLINE CHLORIDE, CHROMIUM PICOLINATE.***"


Margaret A. Smithers, 264
Investigator, 

000024

TO: Lori Love, M.D., Ph.D.

FROM: Constance J. Hardy 

DATE: 7/8/99

SUBJECT: ARMS 12851

This memo pertains to additional information concerning Adverse Event 12851 which involved the reported use of several dietary supplements including Ripped Force. In the adverse event file there is no indication as to how the Ripped Force photocopied labels of Sample Number 98-688-719 were obtained; consequently Ms. Smithers, KAN-DO investigator for AER 12851 was asked several questions via telephone to provide additional information. Ms. Smithers clarified that Exhibit 1, a blown-up partial copy of a label was provided from the friends of the AER 12851 consumer Mr. [REDACTED] (22 year old male). This label did not come from a bottle that Mr. [REDACTED] had consumed. Rather, it was a product bottle label unrelated to Mr. [REDACTED] his friends were very familiar with his use of the product during his workouts at the gym. The second blown-up photocopied label of Ripped Force was obtained from a bottle provided by [REDACTED] [REDACTED] (where the adverse event occurred and where Ripped Force could be purchased) to Mr. David Foran (913-752-2163), also a KAN-DO investigator.

000025